REMARKS

Claims 1 – 7, 9, and 10 are currently pending, with Claims 6, 7, 9, and 10 having been withdrawn from consideration and Claims 1 – 5 having been considered on the merits. Claims 16-19 are new. No new matter has been added by the addition of the three new claims, all of which are fully supported in the specification in the third and fourth full paragraphs of the detailed description section. Claims 1 – 5 were rejected under Section 103 as allegedly obvious over Miyazawa taken in combination with U.S. Patent No. 6,395,300 to Straub.

Each of the foregoing rejections is respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

As the Applicants have stressed before, each of Claims 1 – 5 specifically recites tamsulosin hydrochloride in amorphous form. This is neither disclosed nor suggested by the cited references.

Miyazawa discloses very non-specific "porous drug matrices and methods of manufacture thereof." Miyazawa includes an extensive list of potential so-called "preferable" drugs that are contemplated—found at the bottom of Column 7 and including well over 100 drugs. However, Miyazawa says nothing about the preparation of amorphous tamsulosin hydrochloride. In fact, Miyazawa gives no specific examples or any suggestion whatsoever that an amorphous form of tamsulosin hydrochloride even exists.

Nonetheless, the Examiner asserts an amorphous form of tamsulosin would have been obvious from Straub since, in the Examiner's view, Straub allegedly "discloses a method for producing drugs in a crystalline state, an amorphous state, ***or*** mixtures thereof ... wherein the drugs include tamsulosin hydrochloride." The term "or" was used with good reason in this quoted sentence in Straub because the inventors in Straub no doubt understood that every single one of the hundreds, if not thousands, of drugs one could theoretically conjure from the long lists of drugs and excipients in Straub would not necessarily exist or, in any event, render a desirable composition. Nonetheless, the Examiner is attempting to use Straub to say something that Straub simply does not say—that amorphous tamsulosin hydrochloride exists. There are simply way too many drugs and drug forms contemplated in Straub for the Examiner to reasonably assert Straub as teaching or suggesting to a person having ordinary skill in the art at that time that he or she should "try" to make a heretofore unknown amorphous form of one of hundreds of drugs listed in the Straub reference. The Examiner

simply overstates the teachings of Straub.

Straub is generally directed to porous matrices said to provide enhanced dissolution of drugs. At columns 4 – 8, Straub lists scores of active ingredients which may be used in the practice of his technology and, at column 12, lines 42 – 45, Straub states that some of these drugs may be present in a crystalline form and some in the amorphous form. However, Straub says nothing whatsoever about the existence of tamsulosin hydrochloride in amorphous form.

Straub also plainly does not instruct or even suggest those of skill in the art how to make tamsulosin hydrochloride in the amorphous form. "Although published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill to make and use the invention." *See In re Kumar*, 418 F.3d 1361 (Fed. Cir. 2005). Here, Miyazawa falls very short of such burden.

In addition, Claim 1 has been amended herein to specify that the amorphous tamsulosin hydrochloride is prepared by the lyophilization of tamsulosin hydrochloride from a solution, as opposed to an emulsion or other mixture. More preferably, the amorphous tamsulosin hydrochloride is prepared by lyophilization of tamsulosin hydrochloride from an aqueous solution.

This is contrary to the teachings of the Straub patent, which teaches lyophilization from a mixture comprising both a solvent and an additive which is referred to as a "pore forming agent." According to Straub, the pore forming agent is preferably a liquid which is immiscible with the solvent (Col. 10 Line 59 – 67). Thus an emulsion is formed and tamsulosin hydrochloride is lyophilized from this emulsion rather than a solution. A stabilizer such as a surfactant may also be included in the emulsion. (Col. 12 Line 47 – 50) Alternatively a solid pore forming agent may be used but this agent may also lead to the formation of an emulsion with the solvent or the solid agent may exist as solid particulates in the solvent (Col. 11 Line 13 – 18). Here again, tamsulosin hydrochloride is not lyophilized from a simple solution.

The addition of these additives is significant because their presence is likely to alter the morphology of the tamsulosin hydrochloride produced by the lyophilization process. In other words, the additional presence of the pore forming agents may well lead to formation of a crystalline tamsulosin hydrochloride product, rather than an amorphous product.

Thus, the subject matter of independent Claim 1 is patentable over the cited art. Further, "if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." M.P.E.P. § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)).

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicant hereby petitions for the appropriate extension of time and requests that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355.**

Respectfully submitted,

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